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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,184	11/13/2001	Eyal S. Ron	028.02.140PO2	5706

7590

04/23/2003

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EXAMINER

JONES, DAMERON

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,184

Applicant(s)

RON ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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ACKNOWLEDGMENTS

1. The Examiner acknowledges Paper No. 1 ½, filed 11/13/01, wherein the specification was amended and claims 2-40 were canceled.

Note: Claim 1 is pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to a composition comprising a linear block copolymer having a polyoxyalkylene (containing a hydrophobic region) and at least one biocompatible polymer or oligomer.

DOUBLE PATENTING REJECTION

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,316,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both inventions are directed to compositions comprising a linear block copolymer having a polyoxyalkylene block and a second block containing a bioadhesive polymer or ligand. The claims differ in that the patented invention requires that the polyoxyalkylene having a hydrophobic and a hydrophilic region to be effective form micelles and the response is due to a change in temperature. The instant invention is not limited to the formation of micelles or a specific temperature range.

112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as written is ambiguous because it is unclear what environmental stimulus Applicant's is referring to. Is Applicant claiming that the viscosity changes in response to a change in temperature? If so, please amend the claim as such-

Claim 1 is confusing because of the phrase 'having a hydrophobic region and a hydrophobic region'. In particular, it is unclear if Applicant intended the polyoxyalkylene to contain both a hydro~~phobic~~**phobic** and a hydro~~philic~~**philic** region or if Applicant intended the polyoxyalkylene to have a hydrophobic region only. Please make the appropriate correction in order that one may readily ascertain what is being claimed.

102 REJECTIONS

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (WO 95/24430).

Hoffman et al disclose sensitive block and graft copolymers and methods thereof wherein the pH sensitive polymer component is a carboxylic acid containing polymer such as polyacrylic acid (polyAAc) [page 9, line 23- page 11, line 15; page 13,

lines 22-page 14, line 12]. In addition, Hoffman et al disclose (1) a block copolymer of polyethylene oxide and polypropylene oxide such as Pluronics (page 14, lines 31-36). (2) Suitable block copolymers of the invention of Hoffman et al have a low solution critical temperature ranging from 20 - 40 degrees Celsius at physiological pH (page 4, lines 27-34). (3) Formulations of the copolymer-drug particles for topical administration include solutions, ointments, tablets, capsules, suppositories, creams, and gels wherein the particles in the formulation range from 0.1% to 20% by weight of the total suspension (page 20, lines 27-33; page 21-22, bridging paragraph). (4) The copolymers may be delivered through nasal, vaginal, oral, ocular, rectal, dermal, or otic methods (page 22, lines 17-18). (5) Example 6, pages 48-52, disclose a block copolymer of ethylene oxide and propylene oxide (EO/PO/EO) in combination with AAC. Hence, both Applicant and Hoffman et al disclose a thermally sensitive composition comprising a block copolymer having at least a first block comprising polyoxyalkylene and a second block comprising a biocompatible polymer or oligomer.

Note: Pluronics and poloxamer are equivalent terms.

103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,847,023).

Viegas et al disclose thermal aqueous gels comprising polyoxyalkylene compounds and an ionic polysaccharide (see entire document, especially, abstract; column 1, lines 11-12). The aqueous vehicles containing a polyoxyalkylene block copolymer are liquid at ambient temperatures and transition at mammalian body temperatures to a semi-solid gel (column 4, lines 30-40). In addition, Viegas et al disclose (1) polyphase systems may contain non-aqueous solutes, non-aqueous solvents, and other non-aqueous additives while homogeneous, polyphase systems may contain additives such as water insoluble high molecular weight fatty acids and alcohols, fixed oils, volatile oils and waxes, mono-, di-, and triglycerides, and synthetic water insoluble polymers without altering the functionality of the system (column 3, lines 11-18). (2) The block copolymer compositions comprise at least one polyoxyalkylene block copolymer of formula I (column 4, line 54). (3) The invention also encompasses terminal hydroxyl groups such as poloxamers (column 5, lines 13-18). (4) The polyoxyalkylene compounds may comprise polyoxybutene-based block copolymers and polyoxyethylene-polyoxypropylene block copolymers (column 5, line 19 - column 6, line 13). (5) The polyoxyalkylene block copolymers may be utilized in pharmaceutical composition or aqueous solutions of the polymer gels may be used in combination with surfactants which may be ionic or non-ionic (columns 6-7, bridging paragraph; column 8, lines 3-8; column 9, lines 35-58). (6) The aqueous gels may contain preservatives, co-solvents, suspending agents, viscosity enhancing agents, buffering agents, ionic strength and osmolality adjustors and other excipients (column 10, lines 9-36). (7) Example 1, columns 10-11, discloses a triblock polymer comprising and aqueous solution of polyoxyethylene-polyoxypropylene block copolymer and having a

polyoxypropylene base. (8) Example 2 and 3, columns 11-12, disclose the formation of a thermo-sensitive aqueous system for forming a thermally reversible corneal contact lens wherein the poloxamer blocks are melted at 65 degrees Celsius in water, buffer is added, and the temperature of the mixture is gradually reduced to 25 degrees Celsius, then to 15 degrees Celsius.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a composition comprising a block copolymer wherein at least a first block comprises polyoxyalkylene and a second block comprising a biocompatible polymer or oligomer and pharmaceutical compositions thereof because Viegas et al disclose that it is known in the art to generate thermo-sensitive aqueous gels comprising various polyoxyalkylene composition and an ionic polysaccharide and pharmaceutical compositions thereof as set forth in the paragraphs above.

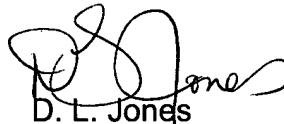
COMMENTS/NOTES

11. Applicant is reminded that the recitation that an element is 'capable of performing a function is not a positive limitation, but only requires the ability to so perform that function (see claim 1, line 3). Thus, it does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

April 21, 2003